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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/462,993 | Kieny, Marie-Paule | |
| | Examiner | Art Unit | |
| | Q. Janice Li | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/17/04.
2. ☒ The allowed claim(s) is/are 45,47,49,57,58,61-63,66-69,72-77 and 79-94.
3. ☒ The drawings filed on 12 February 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |


Q. Janice Li
Primary Examiner
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DETAILED ACTION

The amendment filed on 8/17/04 has been entered. Claims 44, 46, 48, 50-56, 59, 60, 65, 70, 71, 78 have been canceled. Claims 45, 47, 49, 58, 61-63, 66-69, 72-77, 79-81 have been amended. Claims 82-94 are newly submitted. Claims 45, 47, 49, 57, 58, 61-63, 66-69, 72-77, 79-94 are pending in the application, and under current examination.

All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office action mailed 5/17/04 are withdrawn in view of the amendments and the following Examiner's amendment.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher North on October 20, and November 9, 2004.

The claims have been amended as follows:

Claim 45. (currently amended) An antitumoral composition for the treatment of an HPV related cancerous or precancerous condition, wherein the composition comprises ~~comprising~~ at least one recombinant vector, or a viral particle comprising said recombinant vector, wherein

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said recombinant vector ~~comprising~~ comprises a sequence encoding at least one immunogenic polypeptide ~~encoded by the E6 or E7 early region of a HPV-16 papillomavirus genome selected from the group consisting of the E6 polypeptide of the HPV-16 papillomavirus and the E7 polypeptide of the HPV-16 papillomavirus~~, wherein said immunogenic polypeptide is modified by inserting a membrane anchoring sequence and a secretory sequence, so as to have a membrane location at the surface of the cells in which it is expressed, wherein said vector is a non-integrative vector, and wherein said immunogenic polypeptide ~~encoded by the E6 or E7 early region of a HPV-16 papillomavirus genome~~ naturally has a nuclear location and wherein its natural nuclear localization sequence is deleted.

Claim 47. (currently amended) An antitumoral composition for the treatment of an HPV related cancerous or precancerous condition, wherein the composition comprises ~~comprising~~ at least one recombinant vector, or a viral particle comprising said recombinant vector, wherein said recombinant vector ~~comprising~~ comprises a sequence encoding at least one immunogenic polypeptide, wherein said immunogenic polypeptide is modified by inserting a membrane anchoring sequence and a secretory sequence, so as to have a membrane location at the surface of the cells in which it is expressed, and wherein said vector is a non-integrative vector, and wherein said immunogenic polypeptide is a nononcogenic variant of the ~~polypeptide encoded by the E6 early region~~ E6 polypeptide of a HPV-16 papillomavirus genome ~~wherein residues 111 to 115 are deleted comprising the amino acid sequence shown in SEQ ID NO:1 from position 29 to position 181~~ or said immunogenic polypeptide is a nononcogenic variant of the ~~polypeptide encoded by the E7 early region~~ E7 polypeptide of a papillomavirus HPV-16 genome ~~wherein~~

~~residues 21 to 26 are deleted~~ comprising the amino acid sequence shown in SEQ ID NO: 2 from position 26 to 117.

In claim 49, --wherein the composition comprises-- was inserted in place of “comprising” in line 2, and --comprising-- was inserted in place of “having” in line 2 of (3).

Claim 57. (currently amended) A method for the treatment of an HPV related cancerous or precancerous condition in a subject, wherein the method comprises ~~comprising~~ administering an effective amount of the antitumoral composition of claim 47 to said subject to treat said cancerous or precancerous condition ~~cancer or tumor~~ in said subject.

Claim 61. (currently amended) An antitumoral composition for the treatment of an HPV related cancerous or precancerous condition, wherein the composition comprises ~~comprising~~ at least one recombinant vector or a recombinant viral particle comprising said recombinant vector, wherein said recombinant vector comprises ~~comprising~~ a sequence encoding:

(1) an immunogenic polypeptide comprising a sequence shown in SEQ ID NO: 1 and wherein said recombinant vector further comprises a sequence encoding the L1 protein of a papillomavirus and/or the L2 protein of a papillomavirus,

(2) an immunogenic polypeptide comprising a sequence shown in SEQ ID NO: 2, and wherein said recombinant vector further comprises a sequence encoding the L1 protein of a papillomavirus and/or the L2 protein of a papillomavirus, or

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(3) an immunogenic polypeptide comprising a sequence shown in SEQ ID NO: 1, an immunogenic polypeptide ~~having~~ comprising a sequence shown in SEQ ID NO: 2, and wherein said recombinant vector further comprises a sequence encoding the L1 protein of a papillomavirus and/or the L2 protein of a papillomavirus.

Claim 68. (currently amended) A method for the treatment of an HPV related cancerous or precancerous condition in a subject, wherein the method comprises ~~comprising~~ administering an effective amount of the antitumoral composition according to claim 61 to said subject to treat said cancerous or precancerous condition ~~cancer or tumor~~ in said subject.

Claim 72. (currently amended) An antitumoral composition for the treatment of an HPV related cancerous or precancerous condition, wherein the composition comprises ~~comprising~~ at least one recombinant vector or a recombinant viral particle comprising said recombinant vector, wherein said recombinant vector comprises ~~comprising~~ a sequence encoding at least one immunogenic polypeptide, wherein said recombinant vector is a MVA vector and wherein the sequence encoding at least one immunogenic polypeptide comprises:

a first sequence encoding a nononcogenic variant of the ~~polypeptide encoded by the E6 region of HPV-16~~ E6 polypeptide of HPV-16 comprising an amino acid sequence shown in SEQ ID NO:1 from position 29 to position 181, wherein the polypeptide encoded by the E6 region of HPV-16 has residues 111 to 115 deleted and is further modified by insertion of the a secretory and membrane anchoring sequences of the measles F protein, and wherein the first sequence is under the control of a vaccinia virus 7.5K promoter; and,

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a second sequence encoding a nononcogenic variant of the ~~polypeptide encoded by the E7 region of HPV-16~~ E7 polypeptide of HPV-16 comprising an amino acid sequence shown in SEQ ID NO: 2 from position 26 to 117, ~~wherein the polypeptide encoded by the E7 region of HPV-16 has residues 21 to 26 deleted and is further modified by insertion of the a~~ secretory and membrane anchoring sequences of the rabies glycoprotein, and wherein the second sequence is under the control of a vaccinia virus 7.5K promoter; and,

the vector further comprising a third sequence encoding human IL-2, wherein the third sequence is under the control of a H5R promoter.

Claim 73. (currently presented) A method for the treatment of an HPV related cancerous or precancerous condition in a subject, wherein the method comprises ~~comprising~~ administering an effective amount of the antitumoral composition of claim 72 to said subject to treat said cancerous or precancerous condition.

Claim 79. (currently amended) A method for the treatment of an HPV-related cancerous or precancerous condition in a subject, wherein the method comprises ~~comprising~~ administering an effective amount of the antitumoral composition of claim 84 to said subject to treat said cancerous or precancerous condition.

In claim 83, --late-- was inserted in place of "lat" in line 3.

Claim 90. (currently amended) A method for the treatment of an HPV-related cancerous or precancerous condition in a subject, wherein the method comprises ~~comprising~~ administering an effective amount of the antitumoral composition according to claim 49 to said subject to treat said cancerous or precancerous condition ~~cancer or tumor~~ in said subject.

The abstract has been amended as following:

The word --the-- is inserted in place of "said" in line 8.

Claims have been renumbered in an orderly manner and according to 37 C.F.R. 1.126 (see MPEP 608.01 (j) and 608.01 (n)/IV).

Conclusion

Claims 45, 47, 49, 57, 58, 61-63, 66-69, 72-77, 79-94 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

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Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

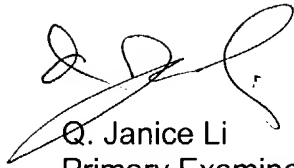
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Q. Janice Li
Primary Examiner
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November 9, 2004